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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,065

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Shinichiro Nishimura

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EXAMINER

BLAND, LAYLA D

ART UNIT

PAPER NUMBER

1623

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,065	Applicant(s) NISHIMURA ET AL.	
	Examiner LAYLA BLAND	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/28/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6-10,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3,6,7,9,10 and 13 is/are allowed.
- 6) ☒ Claim(s) 4,8 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is a response to Applicant's amendment submitted March 26, 2008, wherein claims 2, 5, 11, and 12 are canceled and claims 3, 4, 6-10, and 13-14 are amended. Claims 3, 4, 6-10, and 13-14 are pending and are examined on the merits herein.

In view of the cancellation of claims 2, 5, 11, and 12, all rejections made with respect to that claim in the previous office action are withdrawn.

In view of Applicant's amendment submitted November 28, 2008, the rejection of claims 3, 7, and 13 under 35 USC 112, first paragraph, for new matter with respect to "pentenyl" is withdrawn. The claims have been amended to recite "4-pentenyl."

In view of Applicant's amendment submitted November 28, 2008 and the interview of November 25, 2008, the rejection of claim 13 under 35 USC 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn.

In view of Applicant's amendment submitted November 28, 2008, the rejection of claims 2-14 under 35 USC 112, second paragraph, as being indefinite with respect to the substituent -NO_2 is withdrawn.

In view of Applicant's amendment submitted November 28, 2008, the rejection of claims 4 and 8 under 35 USC 112, second paragraph, for indefiniteness with respect to "a protected asparagines derivative," is withdrawn. The claims now recite a formula for the asparagines derivative.

In view of Applicant's remarks submitted November 28, 2008, the rejection of claim 10 under 35 USC 103(a) as being unpatentable over Takatani et al. in view of

Greene et al. is withdrawn. Applicant's argument that the claimed compound has two beta bonds while Takatani's compound has one alpha and one beta bond is persuasive.

The following new rejection was necessitated by Applicant's amendment submitted November 28, 2008, wherein the protected asparagines formula was added to claims 4 and 8:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 8, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 4, 8, and 14 were amended to incorporate a chemical structure which was not described in the specification. Page 13 of the specification teaches the use of a compound which is Aloc-Asp-OBu^t to afford an asparagine-linked trisaccharide, but that is a different compound than the formula which was incorporated into claims 4 and 8. The abbreviation Asp denotes aspartic acid, not asparagine. The structure incorporated into claims 5 and 8 is drawn as a protected asparagine, not a protected aspartic acid. Thus, the formula incorporated into claims 4 and 8 was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 8, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 8, and 14 recite methods wherein an asparagine derivative (an amide) is reacted with trisaccharide (III) to afford the asparagine-linked trisaccharide (IV). However, the specification, page 13, shows the same reaction with an aspartic acid derivative (an acid), abbreviated as Aloc-Asp-OBu^t. It is unclear which was intended to be claimed.

Allowable Subject Matter

Claims 3, 6, 7, 9, 10, and 13 are allowed. The following is a statement of reasons for the indication of allowable subject matter: The claimed methods and chemical compounds are not taught or suggested by the prior art. The closest prior art is seen to be Gunther et al. (Angew. Chem. Int. Ed. Engle. 29 (1990) No. 9, PTO-1449 submitted September 13, 2006).

Gunther teaches methods for the production of asparagine-linked trisaccharide 11, starting from mannoside 3 and including the intermediate trisaccharides 5-7. The

claimed methods are also methods for producing asparagine-linked trisaccharide starting from a mannose disaccharide and including trisaccharide intermediates, but the starting materials, intermediate trisaccharides, and processes for preparing them are different.

Gunther's mannoside 3 was obtained by inversion of the configuration of glycoside 2 in Scheme 1. In contrast, the claimed methods require hydrolysis of a polysaccharide to obtain the starting mannoside of formula (I), followed by conversion of that product to an azide disaccharide of formula (II) via halogenation/reduction and azidonitration. The azide disaccharide can then be used to form the corresponding trisaccharide of formula (III), which is can be used for preparation of asparagine-linked trisaccharide. This method is different from Gunther's method of producing disaccharide 3 and trisaccharides 5-7, and necessarily results in intermediates of different structures and requiring very different protection/deprotection strategies. Because halogenation/reduction and azidonitration of a mannose disaccharide of claimed formula (I) is not taught or suggested by the prior art either as a stand-alone process or an intermediate process, the claimed methods and intermediates are not seen as obvious over Gunther et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/
Examiner, Art Unit 1623